





Life

FLEXIBLE STUDIES FOR ONCOLOGY (MULTIPLE CYCLES)

Isabelle Laugel
Principal Consultant
Life Sciences Expertise

OHSUG 2013, Miami



Agenda

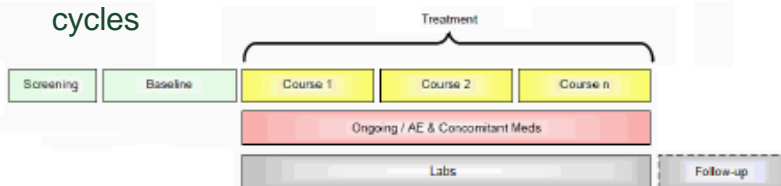
- ☞ Build flexible studies to manage protocols with multiple cycles and/or multiple arms
- ☞ Manage large number of AEs
- ☞ Manage List of Tumors on Assessment Forms
- ☞ Manage Local Labs

Life Sciences Expertise

2

Overview

- In Oncology Studies, there are frequently repeated cycles



- The number of cycles is not always known in advance
- The start of a new cycle may be subject to conditions depending on information recorded at current cycle

Life Sciences Expertise


3

Overview

- AEs are more difficult to handle for Oncology studies, as:
 - ✓ The number of AEs is usually very high
 - ✓ The same AE may occur several times during the study
- Lab data is frequently collected via Local Labs
 - ✓ The OC Lab system does not allow to handle easily Local Lab Assignment
- Some data is usually collected repeatedly, e.g. tumor measurement, and requires multiple entry of the same information
- Unplanned data is frequently collected

Life Sciences Expertise

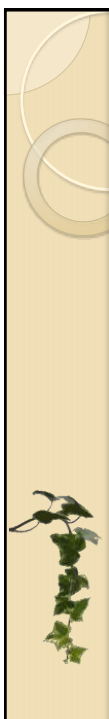
4



Building Flexible Studies

- ✓ Create Intervals
- ✓ Define DCI Rules & Interval Rules
- ✓ Access to Events and DCIs in RDC
- ✓ Manage unexpected DCIs
- ✓ Calculate & Validate Expectedness of DCIs and Events

Life Sciences Expertise 5



Flexible Studies

- Studies in OC may be setup as Flexible in order to allow the creation of interactive DCI Books:
 - ✓ DCIs and intervals may be set to accessible to the User in RDC depending on the Data entered in previous DCIs or intervals
- In order to use this functionality:
 - ✓ The Study must be marked as flexible (before Data Entry started)
 - ✓ The needed Intervals must have been created in OC
 - ✓ DCI Rules and Interval Rules must have been defined in the Enhanced DCI Book

Life Sciences Expertise 6

Creating Intervals

- Intervals may be created from the Easy Study Design screen:



- Or from the Intervals menu



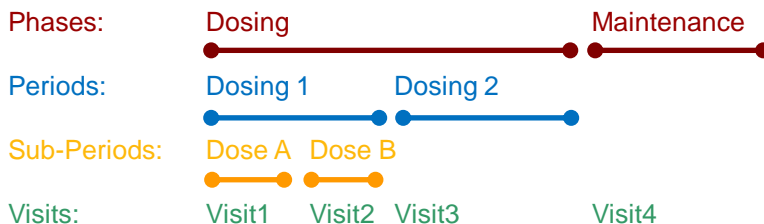
Phase Name	Short Name	Previous Phase	Phase Type	Task Use	Random Acc	Status Type	Visit Type	Minimum Duration	Maximum Duration	Visit Count	Complete ?	Visit Day
Screening	SCREENING		SCREEN	DAY		CLOSED	DOUBLE	0	1		<input type="checkbox"/>	
Baseline	BASELINE	Screening	BASELN	DAY		CLOSED	DOUBLE	0	1		<input type="checkbox"/>	
Dosing	DOING	Baseline	DOING	DAY		CLOSED	DOUBLE	0	1		<input type="checkbox"/>	
Termination	TERMINATION	Dosing	FOLL_UP	DAY		CLOSED	DOUBLE	0	1		<input type="checkbox"/>	

Life Sciences Expertise

7

Creating Intervals

- Intervals in OC consist of phases that may contain Periods and Sub-Periods:



- Periods and Sub-Periods are optional within OC/RDC but may be useful when setting up Flexible Studies

Life Sciences Expertise

8

Creating Intervals

- Periods and Sub-Periods are created from the Phases screen if needed



- All types of Intervals (Phases, Periods and Sub-Periods) may be used to define Interval Rules

Life Sciences Expertise

9

Make a Study Flexible

- Studies are made flexible upon creation:



- Or later in the Conduct → Security → Clinical Study States screen:



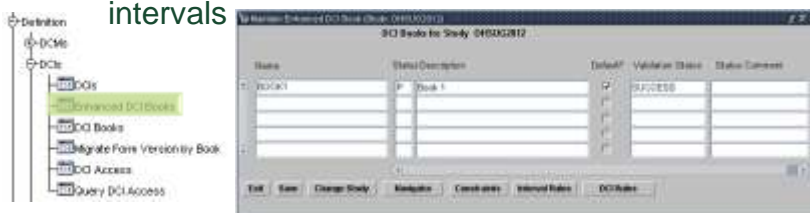
- This setting cannot be changed once Data Entry already started

Life Sciences Expertise

10

Enhanced DCI Book

- In flexible studies, Visits and CRFs are displayed dynamically in RDC depending on data previously entered
- The Enhanced DCI Book screen allows DCI Rules and Interval Rules to be defined:
 - ✓ DCI rules allow to enable individual DCIs
 - ✓ Interval Rules allow to enable one or more intervals



Life Sciences Expertise

11

Interval Rules

- Interval Rules are created to:
 - ✓ Either enable one or more intervals
 - ✓ Or skip one or more intervals
- The Interval Rule can be based
 - ✓ Either on presence of any data on a certain DCI (=Trigger DCI)
 - ✓ Or the response to a non repeated question having a DVG attached
- Any DCI may be selected as a trigger DCI

Life Sciences Expertise

12

Interval Rules

Choose the action to be performed And the appropriate Interval(s)

DCI	DCM (Qual Value)	Condition	Value(s)	OPDS(s) at which Trigger DCI is Defined	Action	Interval(s)
RANDOMIZATI	BLIND	BLIND	YES	DAY 14	Enable	Enable, Termination, Visit
RANDOMIZATI	BLIND	BLIND	NO	DAY 14	Disable	Termination
WALKING SH	CS	VISIT_COMPL	YES	DAY 1	Enable	Week 2
CDI	DELEGATION	VISIT_COMPL	YES	WEEK 2 (WEEK 2)	Enable	Week 2

- Select the Trigger DCI
- And DCM, Question and Value if appropriate To define the condition under which the Interval should be displayed

Sub-windows shown:

- Interval Trigger DCI Name: [Field], DCM Name: [List], Val: [List], Int: [List], Int Date: [List]
- Interval Trigger Question: [Field], Condition Name: [List], DCI: [List], DCI Value: [List]
- Interval Trigger Search Values: [Field], [Field], [Field], [Field], [Field], [Field], [Field], [Field], [Field], [Field]

Interval Rules

- Example:
 - ✓ The presence of the “Course Assessment” DCI at a certain Interval enables the next Interval

Study: [Field] Visit: [Field] Visit Date: [Field] Patient: [Field]

COURSE ASSESSMENT

Start Date of Course: [Field] End Date of Course: [Field]

Response Assessment: [Field] Date of Response: [Field]

Date of Progression: [Field]

Any AE in this Course? Yes No

Interval Rules

- Example (cont.):
 - ✓ Define the corresponding Rule in the DCI Book

When data is present on the Course Assessment Form

The Next Interval is enabled

- ✓ Note that [any data] means “Any Response”, a DCI marked as blank would not enable the next Interval

DCI Rules

- DCI Rules are created to enable one or more DCIs
 - ✓ Either within a Visit
 - ✓ Or across Visits
- Definition of DCI Rules is similar to definition of Interval Rules

For DCI Rules, only DCIs containing non repeated questions with DVGs may be selected as Trigger DCI

The same Target DCI cannot be selected for more than one DCI Rule

Interval and DCI Rules

- All possible Interval Rules and DCI Rules cannot be defined using enterable questions:
 - ✓ Rules for which the Trigger Question is a numeric value or a Date
 - ✓ Rules based on multiple conditions, e.g.
 - Enable DCI when Question A=Yes and Question B=No
 - Enable Next Interval if all mandatory CRFs have been completed
 - ✓ Rules based on DVGs in repeating Question Groups
- In such situations, Derived Questions may be used

Life Sciences Expertise

17

Example of a DCI Rule

- When data for a new Patient is entered:
 - ✓ Initially only the Eligibility and randomization CRFs are displayed:

Select All	Select Item	Patient	Day -14								
Select	Number	Elig	Demo	Health	Payment	Physice Scr	VSI	Eng Screen	Physic Scr	Cold Scr	Rand
<input type="checkbox"/>	K2	1	--	--	--	--	--	--	--	--	11

- ✓ If all Inclusion Criteria are answered Yes and all Exclusion Criteria are answered No, then all CRFs in the Screening Visit are enabled

Life Sciences Expertise

18

Example of a DCI Rule

- Include a Derived Question (with a DVG) in the non-repeating Question Group of the Eligibility DCM



Life Sciences Expertise

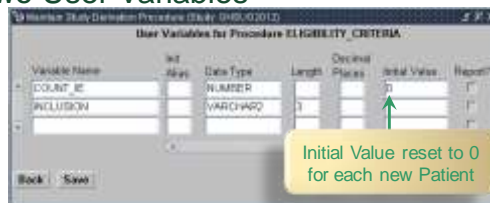
19

Example of a DCI Rule

- Create a Derivation Procedure checking whether all Eligibility Criteria are answered as expected



- Include the two Question Groups in the procedure
- Create two User Variables



Life Sciences Expertise

20

Example of a DCI Rule

- In the Custom Code, count the number of “correct” responses in the repeated Eligibility Criteria

```

IF (QUALIFYING_VALUE=INCLUSION and IE (CORRECT)=YES)
  then COUNT_E = COUNT_E + 1;
ELSE (QUALIFYING_VALUE=EXCLUSION and IE (CORRECT)=NO)
  then COUNT_E = COUNT_E + 1;
end if;
IF COUNT_E = 3 then INCLUSION = 'YES', else INCLUSION = 'NO', end if;
    
```

There are 3 Inclusion Criteria and 3 Exclusion Criteria in this Study

- At the Detail level, assign the value of the User Variable to the Derived Question

Group	Description	Derived Question	Expression
1	Check if all Eligibility criteria are met	INCLUSION	INCLUSION

Example of a DCI Rule

- Define the DCI Rule in the DCI Book:
 - ✓ The remaining DCIs should be displayed only when the derived value is set to Yes

DCI	DCI/Group Value	Question	Value(s)	(STEP) at which Trigger DCI is	Enable DCI	Value Access	DCI	Target
ELIGIBILITY CRT	INCLUSION	INCLUSION	YES	DAY -14	<input checked="" type="checkbox"/>	CPE - CPE	DCI	DAY -14
					<input checked="" type="checkbox"/>		DEMOGRAPHY HDR	DAY -14

This DCI Rule only impacts the first Visit of the Study

Select all DCIs to be collected at Visit Day -14

Example of a DCI Rule

- All CRFs for the Screening Visit are displayed in case the Eligibility Criteria are entered as expected



Life Sciences Expertise

23

Example of a DCI Rule

- Otherwise only Randomization CRF is available

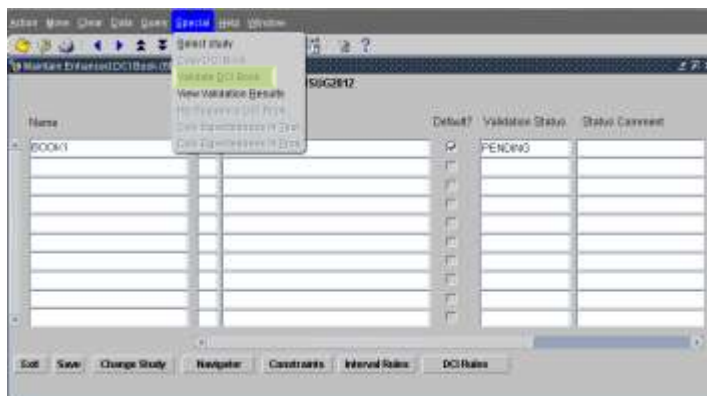


Life Sciences Expertise

24

Validate the DCI Book

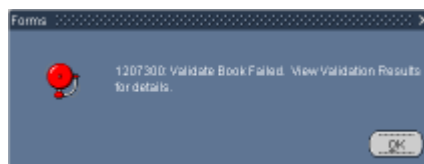
- Once the Enhanced DCI Book is created, and DCI/Interval Rules defined, the DCI Book must be validated



Life Sciences Expertise

Validate the DCI Book

- If any error is found:
 - ✓ A error message is displayed



- ✓ The findings can be reviewed



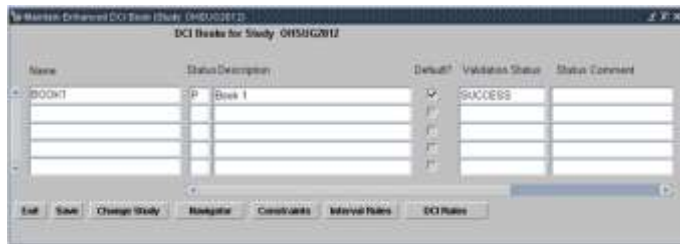
Life Sciences Expertise

Validate the DCI Book

- In case the DCI Book is valid:



- The Validation Status is updated



Life Sciences Expertise

27

Access to Events in RDC

- Once Interval Rules are defined in OC, only Visits matching these rules are accessible in RDC

- Example:

✓ For Patient X1



✓ For Patient X3



Life Sciences Expertise

28

Access to DCIs in RDC

- Once DCIs rules are defined, only DCIs matching the rule are accessible in RDC

The screenshot shows a table with columns: Patient Number, Elig, Consent, Medhist, Physmed, Physexam, and Day -14. Rows are numbered X1 to X7. Callouts point to specific cells:

- Expected DCI entered:** Points to the 'Elig' column for row X1.
- DCI non expected based on rules:** Points to the 'Medhist' column for row X2.
- Unexpected DCI entered:** Points to the 'Physexam' column for row X3.
- Expected DCI not entered yet:** Points to the 'Day -14' column for row X7.

Life Sciences Expertise

29

Unexpected DCIs

- Unexpected pages are managed via the DCI Book

The screenshot shows a dialog box titled 'Maintain DCI Book Constraints for Book BDDK1'. It has tabs for 'Exit', 'Save', 'Change Study', 'Navigator', 'Constraints', 'Interval Rules', and 'DCI Rules'. The 'Constraints' tab is active, showing a table with columns: DCI Name, Planned in Book, Unplanned Use Allowed, and Preferred Version. A callout box explains the 'Unplanned Use Allowed' flag:

Use these two flags to indicate whether unplanned use is allowed:

- Entry of an unplanned page for a visit
- Entry of a second version of a planned page as a subevent

Life Sciences Expertise

30

Unexpected DCIs

- To add unexpected DCIs in RDC:
 - ✓ Select the Patient and
 - ✓ Click on “Add Visit Page” or “Add Other Page”

The screenshot shows the 'Casebook Spreadsheet' interface. At the top, there are filters for 'Visit', 'Casebook', and 'Visit: Day -14'. Below this is a table with columns: Patient, Hq, Dates, MedHist, Payment, Physician, YSI, and SCL. Two callout boxes are present: one pointing to the 'Add Visit Page' button with the text 'Add a new version of a DCI that was planned at this visit and that has already been entered (new subevent)', and another pointing to the 'Add Other Page' button with the text 'Add a DCI that was not planned at this visit'.

Life Sciences Expertise 31

Calculate Expectedness

- The expectedness of DCIs based on the defined rules is automatically calculated when data is entered or modified
- It is also possible to re-calculate the expectedness of DCIs manually

The screenshots illustrate the manual calculation process. The first is a dialog box titled 'Calculate Expectedness in Test' with options for 'DCI Basis' (Current Book, All Books in Current Study) and 'Patients' (All Patients, Only Patients Remaining for Validation). The second shows a 'Special' menu option in the application interface. The third is a confirmation message: 'M31: Calculate Expectedness Completed Successfully'.

Life Sciences Expertise 32

Verify Expectedness

- The information related to the DCIs, Visits and Intervals expected for each Patient is stored in the three tables:

Table Name	Description
PP_EXPECTED_INTERVALS	Planned Intervals for each Patient
PP_EXPECTED_CPES	Planned Visits for each Patient
PP_EXPECTED_DCIS	Planned DCIs for each Patient

- Note that:
 - ✓ The corresponding Audit Trail is stored in the tables [*Table Name*]*\$JN*
 - ✓ Equivalent tables exist in Test Mode (*[Table Name]T*)

Life Sciences Expertise

33


Verify Expectedness

- These tracking tables can be used to produce reports verifying which pages or events are expected for a given patient:

PP_EXPECTED_INTERVALS	PP_EXPECTED_CPES	PP_EXPECTED_DCIS
CLINICAL_STUDY_ID	CLINICAL_STUDY_ID	CLINICAL_STUDY_ID
PATIENT_POSITION_ID	PATIENT_POSITION_ID	PATIENT_POSITION_ID
PLAN_INTERVAL_ID	CLIN_PLAN_EVE_ID	CLIN_PLAN_EVE_ID
BYPASSED_FLAG	DCL_ID	DCL_ID
	CREATION_TS	CREATION_TS
	LAST_EXPECTEDNESS_MOD_TS	

Life Sciences Expertise


34



Other flexible features

- ✓ Define conditional Blocks in Data Entry Layouts to restrict data to be collected
- ✓ Display the Interval in addition to the Visit in RDC

Life Sciences Expertise 35



Conditional Blocks

- Conditional Blocks can be setup for Conditional Branches and Indicator Questions in order to display in RDC only the Questions that should be filled in
- Example:

CRISC SCORING

Assessment Date: / /

PSYCHOTROPIC DRUG TREATMENT HISTORY

List all the Psychotropic drugs the patient received during the past 3 years:

IF NONE, CHECK BOX

Select Drug Name (Enter the Code name for combination drugs)	Frequency	Total Dose	Units	Start Date	Stop Date	Indication	Reason

The Drug Treatment History block of Questions should only be displayed when the "NONE" check box is left blank

Reasons Code

1 No Change

2 Poor

3 Good

Reason for Discontinuation

0 Ongoing

1 Adverse Event

2 Insufficient Response

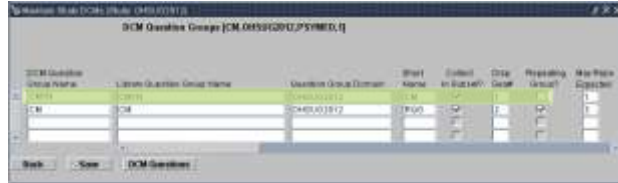
3 Satisfactory Response

99 Other

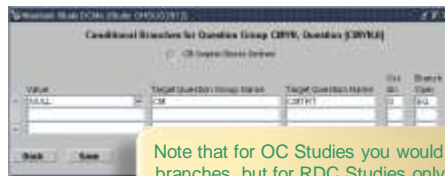
Life Sciences Expertise 36

Conditional Blocks

- Define the “None” Question in a non repeating Question Group

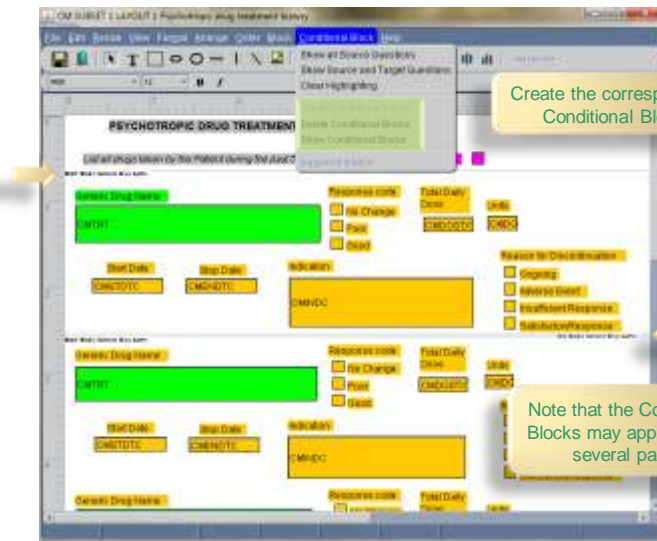


- Define the following Conditional Branch

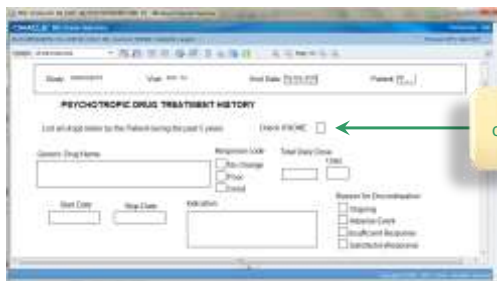


Note that for OC Studies you would define all possible branches, but for RDC Studies only the branch that is not always displayed should be described

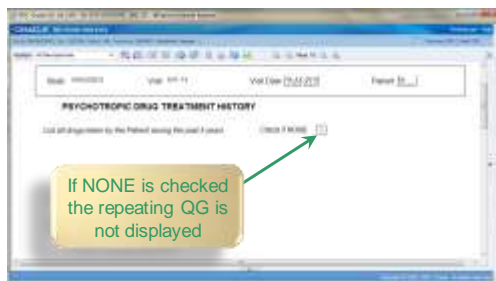
Conditional Blocks



Conditional Blocks



The repeating QG displays if the NONE box is unchecked



If NONE is checked the repeating QG is not displayed

Display the Interval in RDC

- Flexible Studies allow to enable/disable Intervals to match Study Protocols based on multiple courses
 - ✓ However Data Entry is still done at the CPE level and not at the Interval level
- To facilitate the entry of data, the Interval can be displayed in RDC



Setting	Value	Default	Form Local (RDC Setting)	Local DB Value
Display Interval	Y	Y	Y	Y
Display Label for DEM Questions	NO LABEL	LEM	Y	NO LABEL
Display Visit Labels (e.g. V1, V2, P1, P2)	Y	LEM	Y	Y
Enable Entry of Investigator Comments	Y	LEM	Y	Y
Label for customizable patient identifier	REFERENCE	LEM	Y	REFERENCE
Page Labels Compatible with Page Treatment	Y	LEM	Y	Y
Relevant Disabled Display as	DISABLED	LEM	Y	GREYED
Suppress Change Reason for new Responses	Y	LEM	Y	Y
Suppress Change Reason for New Investigator	Y	LEM	Y	Y
Use customizable patient identifier	Y	LEM	Y	Y

Display the Interval in RDC

The screenshot shows the Oracle RDC Online interface. At the top, there are navigation tabs: Home, Casebooks, Review, Reports. Below this, there's a search bar and filters for 'Casebook SpreadSheet', 'Set Visit Focus: Patient', 'Conducts', 'Visit: Day 14', and 'Patients'. A table of patients is displayed with columns for 'Patient', 'Interval', 'Visit', 'Physician', 'VSS', 'VCS', 'Physic', 'Cvss', and 'Status'. A callout box with a green arrow points to the 'Interval' column header, containing the text: 'The Name of the Interval is displayed here'.

Life Sciences Expertise

41

Assign DCI Book to Patients

- ✓ A DCI Book must be assigned to each Patient for RDC Data Entry
- ✓ Several DCI Books may be created for complex study Protocols

Life Sciences Expertise

42

Studies with multiple Arms

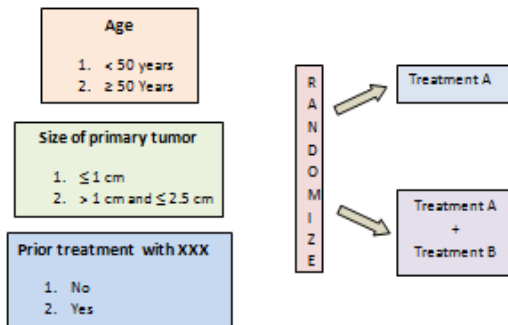
- Designing flexible studies is a way to handle studies with complex protocols
- However depending on the complexity of the DCI and Interval Rules that need to be created, it is sometimes difficult to setup a DCI Book that matches the study Protocol
- It is possible to create multiple DCI-Books in a study and assign the appropriate book to the Patients
 - ✓ Assigning a DCI Book to Patients is required for RDC
 - ✓ This can be done manually, or via a procedure

Life Sciences Expertise

43

Studies with multiple Arms

- Example:



Create one DCI Book for each Arm, and assign the appropriate DCI Book to the Patients based on the Data collected at Screening or Baseline

Life Sciences Expertise

44

Assign a DCI Book to Patients

➤ The usual way to assign a DCI Book to Patients is to use the Patient Positions screen:

✓ Either enter manually the DCI Book name for each Patient



✓ Or Use the “Assign DCI Book” button



Assign a DCI Book to Patients

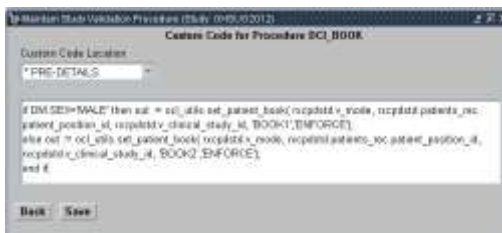
➤ This usual method is not convenient when the DCI Book assigned to the Patients depends on data collected

➤ In this case it is possible to assign a DCI Book to a Patient using a Validation Procedure



Assign a DCI Book to Patients

- In the Custom Code use the procedure `set_patient_book` provided by Oracle and apply any needed condition



- Create a User Variable



Life Sciences Expertise

47

Assign a DCI Book to Patients

- The Detail line of the Validation procedure should not generate any discrepancy:




- Set the Execution Context field to the appropriate value:



Life Sciences Expertise

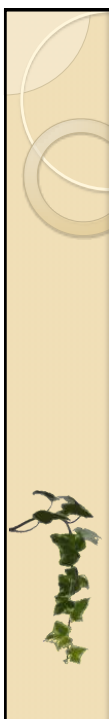
48



Manage Adverse Events

- ✓ The number of AEs per Patient may be very high
- ✓ This may cause troubles when designing the AE form and when updating existing AEs

Life Sciences Expertise 49



Manage AEs

- The first concern regarding Adverse Events is how to setup the forms:
 - ✓ Create one form per AE and one Visit to collect Adverse Event seems the easiest option
 - ✦ However this means that new AEs are created with new subevents, which means the maximum number of AEs per patient is 100
 - ✓ Create one AE form with multiple repeats is a good way to handle data when the number of expected AEs is high
 - ✦ However designing such a layout with many questions and repeats may be difficult during setup and data entry

Life Sciences Expertise 50

Manage AEs

- The first concern regarding Adverse Events is how to setup the forms (cont.):
 - ✓ Create several AE forms or collect AEs at multiple Visits (for example one visit per cycle) seems a nice setup alternative
 - + However when updating AEs (entry of resolution or followup information) the site user may have troubles to find the correct AE



Life Sciences Expertise

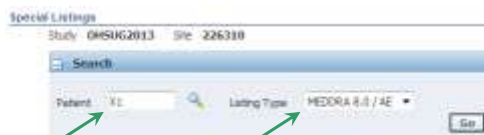
51

Manage AEs

- The Special Listing View in RDC allows to review all AEs and retrieve a page that needs to be updated



- Select the Patient and the type of data you want to review:



The Special Listing View only displays data for one specific Patient

Any data collected on a page that is coded may be displayed

Click on Go

Life Sciences Expertise

52

Manage AEs

- All AEs for the selected Patient are listed:

The screenshot shows a table titled "PEDIA 8.0 / AE for Patient 83" with columns: Name, Visit Date, CRF Name, CRF Stop, Verbatim Term, Auxiliary Information, and Open CRF. The table lists several adverse events such as HEADACHE, ZINGONIA, LOST SNU, NAUSEA, and PERSISTENT COUGH. Callouts provide instructions: "Records may be sorted by clicking on the header (e.g. Verbatim Term or Visit Name)", "All data entered for the AE is shown", and "Once the CRF to be updated is identified, data can directly be updated from this screen".

Name	Visit Date	CRF Name	CRF Stop	Verbatim Term	Auxiliary Information	Open CRF
ADVERSE EVENTS	02-Aug-2013	AE1		HEADACHE	Are there any AEs: Y Serious AE - Yes/No: N AE intensity: 2 Frequency: 3 Relation: 2 Start Date: 02-AUG-2013 Stop Date: Outcome: Action Taken: 2	[Icon]
		AE1	1	ZINGONIA	Are there any AEs: Y Serious AE - Yes/No: Y AE intensity: 2 Frequency: 2 Relation: 2 Start Date: 01-JUL-2013 Stop Date: 15-JUL-2013 Outcome: 1 Action Taken: 4	[Icon]
		AE1	4	LOST SNU	Serious AE - Yes/No: N AE intensity: 2 Frequency: 1 Relation: 1 Start Date: 02-AUG-2013 Stop Date: Outcome: Action Taken: 2	[Icon]
ADVERSE EVENTS	02-Aug-2013	AE1	2	NAUSEA	Serious AE - Yes/No: N AE intensity: 1 Frequency: 2 Relation: 3 Start Date: 01-AUG-2013 Stop Date: Outcome: Action Taken: 1	[Icon]
ADVERSE EVENTS	02-Aug-2013	AE1	3	PERSISTENT COUGH	Serious AE - Yes/No: Y AE intensity: 2 Frequency: 3 Relation: 1 Start Date: 02-AUG-2013 Stop Date: Outcome: Action Taken: 1	[Icon]
ADVERSE				BRONCHITIS		
ADVERSE				ULCER STOMACH		
ADVERSE				REACT		

- Alternative solution: Create a new Activity to be displayed on the Home Page

Manage List of Tumors

- ✓ At each cycle there is usually a tumor assessment form listing all tumors previously evaluated
- ✓ This list is usually entered manually, but may be derived (if not batch loaded)

Manage List of Tumors

- The Tumor Assessment CRF usually looks like this:

The screenshot shows a web-based CRF titled "TUMOR EVALUATION". At the top, there are fields for "Study: OHSUG2010", "Visit: DVY-14", "Visit Date: 01-Jul-2010", and "Patient: 00111111111111111111". Below this is a table with the following columns: "Lesion Number", "Description of Lesion", "Date of evaluation", "Method of Measurement", and "Lesion Size". The table contains three rows of data. A callout box with a green border and text "This information is re-entered at each cycle" has two green arrows pointing to the "Lesion Number" and "Description of Lesion" fields in the first row.

Lesion Number	Description of Lesion	Date of evaluation	Method of Measurement	Lesion Size
0001	0001	01-Jul-2010	001	0001
0002	0002	01-Jul-2010	002	0002
				0000

Life Sciences Expertise

55

Manage List of Tumors

- If the data is batch loaded, it is easy to incorporate a preprocessing check verifying that the Lesion Number, Location, and/or Description are consistent across cycles
- However when the data is entered manually, it would be more convenient to be able to enter this list only once and then display automatically the information on further cycles
 - ✓ Default Values cannot be used for that
 - ✓ Create a Thesaurus DVG would not help to ensure that the data is properly entered at each cycle as the data depends on the patient

Life Sciences Expertise

56

Manage List of Tumors

- Create a derivation procedure might help, but:
 - ✓ Either the Site User enters the assessment data without seeing the Lesion Description, as a derivation procedure can only be executed when saving the page
 - ✓ Or the User opens simultaneously a previously completed Tumor Assessment form to view the Lesion details

A screenshot of a 'TUMOR EVALUATION' form. The form has several input fields and checkboxes. A yellow callout box with the text 'First Cycle' is overlaid on the form, pointing to a specific field.

A screenshot of a 'TUMOR EVALUATION' form, similar to the one above. A yellow callout box with the text 'Next Cycle' is overlaid on the form, pointing to a specific field.

Life Sciences Expertise

57

Manage List of Tumors

- To create such a procedure:
 - ✓ Create two subsets for this DCM

DCM Name	Subset #	Layout #	Name	Domain	Status	Short Name	Type	Description
TUMOR_ASSESSME	1	1	TABS1	OHSUG2012	A	TABS	PHYSICAL EXAM	Tumor Assessment
TUMOR_ASSESSME	2	1	TABS2	OHSUG2012	F	TABS	PHYSICAL EXAM	Tumor Assessment

- ✓ Subset 1 is used to collect the initial data:

Question Name	Question Domain	Occ	Disp	Sec#	Seq#	Date	Year	Required in DCM?	Collect in Study?	Collect in Subset?	Derived?	Editable?	Deleted?
LESION_NUMBER	OHSUG2012	01						✓	✓	✓		✓	
LESION_DESCRIPTION	OHSUG2012	01						✓	✓	✓		✓	
EVALUATION_DATE	OHSUG2012	01						✓	✓	✓		✓	
MEASUREMENT_METHOD	OHSUG2012	01						✓	✓	✓		✓	
LESION_SIZE	OHSUG2012	01						✓	✓	✓		✓	
LESION_NUMBER_DCR	OHSUG2012	01						✓	✓	✓		✓	
LESION_DESCRIPTION_D	OHSUG2012	01						✓	✓	✓		✓	

• Data is entered in the enterable questions
 • And also derived into the corresponding derived questions

- ✓ Subset 2 does not use at all the two enterable questions

Life Sciences Expertise

58

Manage List of Tumors

- When creating the procedure:
 - ✓ Set the Execution Context to “ON-LINE/DCM”:

Procedure Name	Domain	Version	Status	Order	Exec Context	Description
TUMOR_ASSESSMENT	OHSUG002	0	A	100	ON-LINE/DCM	Tumor Assessment derivation
TUMOR_ASSESSMENT	OHSUG002	0	P	100	ON-LINE/DCM	Tumor Assessment details

- ✓ Include the Question Group twice (once for the initial data and once for the new data):

Alias	Event	Qualif	Qualif	Qualifying Expression	Where Clause Extension
TUM					
PREV	TUM	PREVIOUS			RES.REPEAT_SH = T

- ✓ Include the 4 Questions in each Procedure QG:

Question Name	DCM Domain	Order#	Question T	Report?	Aggregate Function	Include List Range?
LESION_NUMBER		0	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
LESION_DESCRIPTION		0	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
LESION_NUMBER_DER		0	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
LESION_DESCRIPTION_D		0	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>

Life Sciences Expertise

59

Manage List of Tumors

- When creating the procedure (cont.):
 - ✓ You need to create two User Variables:

Variable Name	Alias	Data Type	Length	Default	Initial Value	Report?
LES_DESC	TUM	VARCHAR2	200			<input type="checkbox"/>
LES_NUMBER	TUM	NUMBER				<input type="checkbox"/>

- ✓ Assign a value to the User Variables in the Custom Code:

```

Custom Code Location
PRE-DETAILS
if TUM.VISIT_NUMBER = 1 then begin
  LES_NUMBER = TUM.LESION_NUMBER;
  LES_DESC = TUM.LESION_DESCRIPTION;
end;
else begin
  LES_NUMBER = PREV.LESION_NUMBER_DER;
  LES_DESC = PREV.LESION_DESCRIPTION_D;
end; end if;
    
```

- ✓ And define the Details:

Order#	Derivation Question	Expression
1	TUM.LESION_NUMBER_C	LES_NUMBER
2	TUM.LESION_DESCRIPTOR	LES_DESC

Life Sciences Expertise

60

Manage List of Tumors

- Once the Site User enters new Tumor Assessment data and saves the page

The screenshot shows a web form titled "TUMOR EVALUATION". It has a header with "Page: 0000000" and "Page: 001". Below the header, there are four rows of input fields. The first row is for "Lesion" and "Location", the second for "Date of Onset" and "Assessment", and the third and fourth rows have empty fields. Each row has a "Save" button to its right.

- The Lesion information previously entered is automatically populated:

The screenshot shows the same "TUMOR EVALUATION" form. The "Lesion" and "Location" fields in the first row are now populated with text. The "Date of Onset" and "Assessment" fields in the second row are also populated. The "Save" buttons are still present.

Life Sciences Expertise

61

Manage Local Labs

- ✓ Lab data is frequently collected via Local Labs
- ✓ Assigning the correct Lab when having a long list of Labs is a difficult task particularly if done in RDC

Life Sciences Expertise

62

Manage Local Labs

- The management of Local Labs may be facilitated by using Thesaurus DVGs and restricting the values displayed to the current study and site
 - ✓ Define a Thesaurus DVG Listing Labs by address and link Labs to Sites by location (e.g. country, state..)
 - ✓ Add a Question in the Lab DCM having this Thesaurus DVG assigned
 - ✓ The Site User will see only the list of Local Labs (or enter a new Lab name)
 - ✓ Then derive the selected Lab Name (if found in the DVG) to the Lab field in the DCM Header

Life Sciences Expertise

63

Manage Local Labs

- Example:
 - ✓ You first need to create a view:

```

SQL> create view LABS_LDC as
select labs.lab, labs.lab_name, labs.country,
sites.clinical_study_id, sites.site_id
from ora_lab_labs labs, dc1study_sites sites, dc1sites s
where s.site_id = sites.site_id and sites.country = labs.country
and to_char(clinical_study_id) like nv(to_char(oc_rtes_dvg_client.get('clinicalstudyid'), 'N'))
and to_char(site_id) like nv(to_char(oc_rtes_dvg_client.get('siteid'), 'N'));
    
```

In this example, "Local" means "in the same country"!

- ✓ And define the matching Thesaurus DVG in OC:

Life Sciences Expertise

64

Manage Local Labs

➤ Example (cont.):

- ✓ In RDC, the Site User can select a Lab from the List:



- ✓ A Discrepancy is created when another Lab is entered manually



Life Sciences Expertise

65

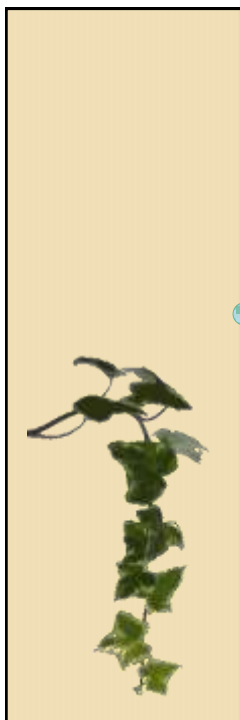
Manage Local Labs

➤ To fill-in properly the Lab field in the DCM Header:


- ✓ You need to use a **Validation** Procedure
- ✓ Enter the SQL code populating the Lab field based on the entry of the Site User in the Custom Code
- ✓ Leave the Lab field blank in case a Thesaurus DVG was created upon Data Entry
- ✓ Create a Detail that does not produce any discrepancy (e.g. Expression = false)

Life Sciences Expertise



66




*Life
Sciences
Expertise*



Questions?



Isabelle.Laugel@LifeSciencesExpertise.com



Biography

- Isabelle Laugel has a background of mathematician and software developer specialized in security of computer systems and optimization
- She is working in the pharmaceutical industry since 15 years and provides training, validation, consulting and support services for Life Sciences applications and business processes to pharmaceutical companies, medical devices companies and CROs of any size worldwide
- She founded Life Sciences Expertise in 2011 in order to share her experience in Data Management and Drug Safety

Life Sciences Expertise

68